UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,297	03/01/2005	Takeshi Matsuda	707550.000290	6278

29540 7590 03/01/2011

DAY PITNEY LLP
7 TIMES SQUARE
NEW YORK, NY 10036-7311

EXAMINER	
WHITE, DENNIS MICHAEL	
ART UNIT	PAPER NUMBER
1772	

NOTIFICATION DATE	DELIVERY MODE
03/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rschneider@daypitney.com
kmcwha@daypitney.com
psorge@daypitney.com

Office Action Summary	Application No.	Applicant(s)	
	10/526,297	MATSUDA ET AL.	
	Examiner	Art Unit	
	DENNIS M. WHITE	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-7 and 9-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-7 and 9-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on 12/16/2010 is acknowledged. Claims 1, 6-7, and 13 are amended. Claims 3 and 19 are cancelled. Currently claims 1, 5-7, 9-18 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims **1** and **9-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anaokar et al (USP 7,494,818) in view of Vogel et al (USP 4,816,224).

Regarding claims **1, 9-10**, Anaokar et al teach a multilayer test strip and producing the test strip that measures concentrations of multiple analytes from a single whole blood sample comprising a top disbursement layer 38 (“water absorbent carrier”), a blood separation layer 40 (“penetration layer”), and stacks 42. Stacks 42 are exposed by holes 34 (“exposed upper surface") and comprise reagents that produce a colored response (Fig. 4) (“plurality of coloration pads” “arranged in a matrix”). The stacks can be used to measure total cholesterol, glucose, and other analytes (col. 9 line 34-col. 10 line 34) (“wherein at least two of the plurality of coloration pads differ from each other with respect to coloration components for allowing measurement of a plurality of items”). Fluid flows in the layer 38 in the lateral direction, whereas the fluid flows only in the perpendicular direction in the layers 40 (col. 7 lines 58-65) (“penetration layer is formed with a plurality of thicknesswise extending pores for allowing the sample liquid to penetrate thicknesswise"). The disbursement layer 38 is exposed by window 32 (“non-laminated”) in which the sample can be applied as well as not completely covered by the blood separation layer (Fig. 6: 110 does not fully cover layer 38). Anaokar et al is

silent that the layer 38 is non-laminated by the blood separation layer 40 extending beyond the penetration layer in the planar direction of the penetration layer for exposure to apply the liquid sample from the upper surface of the layer 38, the sample applying portion of the water absorbent carrier being not covered at all by the penetration layer.

Vogel et al teach a device for separating plasma or serum from whole blood and analyzing the same. Vogel teach the diagnostic agent according to the present invention can be constructed in such a manner that onto the substrate 2, an absorbent material 9 is first applied, such as cellulose paper or a synthetic fibre fleece. Above this material, the glass fibre paper 3 and the reaction layer 1 are applied. The absorbent material 9 can have the same surface area as the reaction layer (FIG. 10) or can have a larger surface area so that the material 9 has an uncovered area (FIG. 9). The blood 8 is droped on to the uncovered surface area of the absorbent material (FIG. 9) or directly next to the absorbent material (FIG. 10) and rapidly taken up by this and sucked under the glass fibre paper. Subsequently, due to the absorbency of the glass fibre paper, blood is sucked upward through the glass fibre paper, separation of the erythrocytes thereby taking place, and plasma passes into the reaction layer 1. The reaction is, as in FIG. 4, observed from the upper side of the rapid diagnostic agent (col. 5 lines 31-50). It is advantageous to provide an uncovered surface area of the absorbent material so that the sample can be applied to the same side as the reaction layer in order to avoid the need to flip the device over to observe the results.

Combining prior art elements according to known methods to yield predictable results is known. Therefore it would have been obvious to one of ordinary skill in the art

to combine the uncovered surface area of the absorbent material to provide the above advantage of being able to apply the sample to the same side as the reaction layer in order to avoid the need to flip the device over to observe the results.

4. Claims **5-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anaokar et al (USP 7,494,818) in view of Vogel et al (USP 4,816,224) and further in view of Ray et al (USP 6,258,045).

Anaokar/Vogel teach the limitations of claim 1 as per above.

Regarding claims **5-7**, Anaokar et al teach the blood separation comprises pores that allow the fluid to pass only perpendicular to the plane of the membrane. Anaokar et al are silent that the plurality of pores have a size of 0.1 to 12 micrometers; wherein the porosity is 4 to 20%; and wherein the membrane is formed by track etching.

Ray et al teach a biological collection device comprising an application member 114 ("water absorbent carrier") facing a separation member 118 ("penetration layer is laminated on a water absorbent carrier that spreads the sample liquid in the planar direction of the water absorbent carrier for drawing up by the penetration layer") (Fig. 4I) that can be track etched Cyclopore membrane material (col. 12 lines 40-45) ("porosity of 4 to 20%" is a property of the Cyclopore membranes). The pores are 0.2 to 5 microns in diameter. It is desirable to provide a blood separation layer that has track etched pores of 0.2 to 5 microns in size and with a porosity of 4 to 20% because it allows the separation of red blood cells from the analytes of interest.

Simple substitution of one known element for another to obtain predictable results is held to be obvious. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the blood separation membrane of Anaokar et al with the blood separation membrane comprising track etched Cyclopore membrane material with 0.2 to 5 microns in diameter of Ray et al because they are known blood separation membranes that flow liquid in a perpendicular direction and separate red blood cells from the analyte of interest to avoid inference of the cells during analysis.

5. Claims **11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anaokar et al (USP 7,494,818) in view of Vogel et al (USP 4,816,224) and further in view of Iwata et al (US 2001/0028862).

Anaokar/Vogel teach the limitations of claim 1 as per above.

Regarding claims **11-12**, Anaokar et al teach after the impregnation solution is added to the layer 102 ("coloration pad") the strips were slit into 0.2 inch (~5mm) strips in preparation for assembly. Anaokar et al is silent that the surface area of the coloration pad is 2.0~15mmx2.0~15mm wherein the specific region accounted for the respective coloration pads is no more than 2.0mm^2.

Iwata et al teach a test device and method of producing the device for a multi-items where in all the test papers for all items for one test are wetted by one shot dropping and transportation of a detecting part or a test device is not required upon measurement. The reaction zone for the horizontal line is preferably 8mm to 2cm and the vertical line is preferably 4 to 10mm. The diameter of the micro test papers

("coloration pads") is being 0.5 mm ("wherein the surface area of the specific region accounted for by the respective coloration pads is no more than 2.0 mm^2") (Para. 0082 and 0084). It would have been desirable to have the dimensions of the total surface area of the reaction zone and the micro test papers ("coloration pads") within this range because having the micro test papers size too large, it becomes difficult to wet the test papers for the whole items by one shot dropping of the sample (Para. 0084).

Therefore it would have been obvious to one of ordinary skill in the art to provide Gibson et al device with the dimension of the surface area of the region of the reaction zones or region ("the plurality of coloration pads") within 2.0-15 mm x 2.0-15 mm and wherein the surface area of the specific region accounted for by the respective coloration pads is no more than 2.0 mm^2 because it provides the above advantages of one shot dropping of the sample.

6. Claims **13-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anaokar et al (USP 7,494,818) in view of Goerlach-Graw et al (USP 5,424,220) and further in view of Vogel et al (USP 4,816,224).

Regarding claims **13-14**, Anaokar et al teach forming the device as in claim 1 supra. Anaokar further teach the impregnation of the reagents in the reaction layers is accomplished by submersing the membrane in the solution and then drying. Anoakar et al are silent that the reagent liquid is coated using a non-contact dispenser such as an injet type.

Goerlach-Graw et al teach an analysis element comprising a chromatographic porous carrier, reaction zone, detection zone, and absorptive zones. The reagents can be applied with screen printing or ink-jet printing (Abstract). It is desirable to use an ink-jet printing because it allows the application of smaller portions of reagent liquid in very small space in the form of compartments which are close together but nevertheless spatially separated (col. 6 lines 30-33).

Therefore it would have been obvious to one of ordinary skill in the art as motivated by Goerlach-Graw et al to use an ink-jet printer to print the reagents in place of the submersing of Anaokar et al in order allow the application of smaller portions of reagent liquid in very small space in the form of compartments which are close together but nevertheless spatially separated.

Anaokar/Goerlach-Graw are silent that the layer 38 is non-laminated by the blood separation layer 40 extending beyond the penetration layer in the planar direction of the penetration layer for exposure to apply the liquid sample from the upper surface of the layer 38, the sample applying portion of the water absorbent carrier being not covered at all by the penetration layer.

Vogel et al teach a device for separating plasma or serum from whole blood and analyzing the same. Vogel teach the diagnostic agent according to the present invention can be constructed in such a manner that onto the substrate 2, an absorbent material 9 is first applied, such as cellulose paper or a synthetic fibre fleece. Above this material, the glass fibre paper 3 and the reaction layer 1 are applied. The absorbent material 9 can have the same surface area as the reaction layer (FIG. 10) or can have a

larger surface area so that the material 9 has an uncovered area (FIG. 9). The blood 8 is droped on to the uncovered surface area of the absorbent material (FIG. 9) or directly next to the absorbent material (FIG. 10) and rapidly taken up by this and sucked under the glass fibre paper. Subsequently, due to the absorbency of the glass fibre paper, blood is sucked upward through the glass fibre paper, separation of the erythrocytes thereby taking place, and plasma passes into the reaction layer 1. The reaction is, as in FIG. 4, observed from the upper side of the rapid diagnostic agent (col. 5 lines 31-50). It is advantageous to provide an uncovered surface area of the absorbent material so that the sample can be applied to the same side as the reaction layer in order to avoid the need to flip the device over to observe the results.

Combining prior art elements according to known methods to yield predictable results is known. Therefore it would have been obvious to one of ordinary skill in the art to combine the uncovered surface area of the absorbent material to provide the above advantage of being able to apply the sample to the same side as the reaction layer in order to avoid the need to flip the device over to observe the results.

Regarding claims **15-16**, Anaokar/Goerlach-Graw/Vogel teach the reaction layers are in a matrix arrangement and at least two of the reaction layers differ from each other with respect to the coloration components (col. 9 line 34-col. 10 line 34)

7. Claims **17-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anaokar et al (USP 7,494,818) in view of Goerlach-Graw et al (USP 5,424,220) and Vogel et al (USP 4,816,224) and further in view of Iwata et al (US 2001/0028862).

Anaokar/Goerlach-Graw/Vogel teach the limitations of claim 13 as per above.

Regarding claims **17-18**, Anaokar/Goerlach-Graw teach after the impregnation solution is added to the layer 102 ("coloration pad") the strips were slit into 0.2 inch (~5mm) strips in preparation for assembly. Anaokar et al is silent that the surface area of the coloration pad is 2.0~15mmx2.0~15mm wherein the specific region accounted for the respective coloration pads is no more than 2.0mm^2.

Iwata et al teach a test device and method of producing the device for a multi-items where in all the test papers for all items for one test are wetted by one shot dropping and transportation of a detecting part or a test device is not required upon measurement. The reaction zone for the horizontal line is preferably 8mm to 2cm and the vertical line is preferably 4 to 10mm. The diameter of the micro test papers ("coloration pads") is being 0.5 mm ("wherein the surface area of the specific region accounted for by the respective coloration pads is no more than 2.0 mm^2") (Para. 0082 and 0084). It would have been desirable to have the dimensions of the total surface area of the reaction zone and the micro test papers ("coloration pads") within this range because having the micro test papers size too large, it becomes difficult to wet the test papers for the whole items by one shot dropping of the sample (Para. 0084).

Therefore it would have been obvious to one of ordinary skill in the art to provide Gibson et al device with the dimension of the surface area of the region of the reaction zones or region ("the plurality of coloration pads") within 2.0-15 mm x 2.0-15 mm and wherein the surface area of the specific region accounted for by the respective

coloration pads is no more than 2.0 mm^2 because it provides the above advantages of one shot dropping of the sample.

Response to Arguments

8. Applicant's arguments with respect to claims 1, 5-7, 9-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, In Suk Bullock can be reached on (571) 272-5954. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dennis M White/
Examiner, Art Unit 1772
/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1773